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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/108,189	07/01/1998	HOWARD TANNER	23660-00611	9021

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WASHINGTON, DC 20007

EXAMINER
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HAN, MARK K

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/108,189

Applicant(s)

TANNER ET AL.

Examiner

Mark K. Han

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 104-109, 115 and 120-135 is/are pending in the application.
- 4a) Of the above claim(s) 104-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 115 and 120-135 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2000 and 01 July 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 104-109 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 05 December 2002.

2. This application contains claims 104-109 drawn to an invention nonelected with traverse in the reply filed on 05 December 2002. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 115 and 120-135 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,885,238 to Stevens et al. (hereinafter 'Stevens') in view of U.S. Patent No. 5,407,434 to Gross.

Stevens teaches the treatment of aneurysms (col. 17, line 9) using two sheaths (broadly shown in Figure 6, the reference generally teaching that any of a number of instruments may be inserted through the sheaths; see col. 17, line 9). Stevens also teaches an inflatable cuff (Fig. 6)

to hold a sheath in place, and a hemostasis valve (col. 42, line 39). Stevens also teaches the use of a guidewire (col. 7, line 11).

Stevens, however, does not teach the use of 'gel-like' material. Gross teaches a similar device for sealing body-inserted instruments and uses a gel to seal around the instruments. The gel also seals the passage completely when the instruments are removed. It would have been obvious to one of ordinary skill in the art to modify the reference of Stevens by including the gel-like valve of Gross as a substantially equivalent alternative to the hemostatic valve.

Stevens and Gross, teach all the claimed subject matter except for repeating the insertion and removal of the aneurysm repair apparatus. However, it is commonly necessary for instruments to be inserted and removed from an introducer sheath(s) several times during the course of a surgical procedure. In fact, Stevens teaches in the abstract that the device may be used for aortic valve repair involving removal of the valve and replacement with a prosthetic valve. The removal, of course, would require removal of the tool, and the replacement would require reintroduction of tools. It would have been obvious to one of ordinary skill in the art to repeat the insertion and removal of the aneurysm repair tools, particularly if the repair was not successfully completed on the first attempt.

#### *Response to Arguments*

4. Applicant's arguments filed 06 September 2005 have been fully considered but they are not persuasive.

Applicant's first argument is on the basis that the Stevens device does not teach a sealing cavity where the existence of a sealing cavity would destroy the Stevens device's function of

openly passing fluids. See remarks filed 06 September 2005, p. 10, lines 10-22. The rejection above clearly shows that Stevens teaching a sealing member and modifying the sealing member with a cavity having a gel-like material would be considered as a functionally equivalent alternative. Further, Stevens does teach the ability of the device to openly pass fluids. This is done through an access port. See col. 42, lines 35-37. It is considered that such a modification would not destroy the invention of Stevens.

In response to Applicant's second argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Gross teaches a device where an instrument is inserted through a cavity containing gel-like material so that fluids will not leak out through the proximal end of the sheath during operation. See the Gross abstract. One of ordinary skill in the art would immediately recognize that such a sealing cavity would be a functionally equivalent alternative to hemostatic valves. The sealing cavity of Gross and the hemostatic valve of Stevens are located at the proximal end of the sheath and they both provide the function preventing fluids from leaking out through the proximal end of the sheath during operation.

*Conclusion*

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark K. Han  
Patent Examiner  
Art Unit 3767

mkh  
November 28, 2005

**KEVIN C. SIRMONS**  
**PRIMARY EXAMINER**

